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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/558,514	11/28/2005	Rajesh Kshirsagar	11336.1010USWO	6285

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EXAMINER	
DEES, NIKKI H	

ART UNIT	PAPER NUMBER
1794	

MAIL DATE	DELIVERY MODE
08/31/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/558,514	KSHIRSAGAR ET AL.	
	Examiner	Art Unit	
	Nikki H. Dees	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in India on June 22, 2005. It is noted, however, that applicant has not filed a certified copy of the 743/MUM/2005 application as required by 35 U.S.C. 119(b).

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It was not executed in accordance with either 37 CFR 1.66 or 1.68.

Claim Objections

3. Claims 1, 2, 4, 6-8 and 10 are objected to because of the following informalities:

Claim 1, line 2 insert “a” after “or”; line 3 change “agent” to “agent(s)”;

Claim 2 line 1 change "comprises" to “comprise”;

Claims 4 and 6 change "or" after "powdered cellulose" to "and" See MPEP § 2173.05(h);

Claim 7 line 2 change "and" to "which";

Claims 8 and 10 need to be rewritten so that "[E]ach claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations." See MPEP § 608.01(m).

Appropriate correction is required.

4. Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 8 requires a "suitable solvent system" for dissolving the sucralose. Claim 9 limits the solvent system to aqueous, non-aqueous, or hydro-alcoholic. Requiring the solvent system to be "aqueous, non-aqueous, or hydro-alcoholic" is not considered to limit the solvent system as any solvent used would either be aqueous or non-aqueous.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 3, 8 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 1 uses the transitional phrase "constituting of." It is unclear what, if any, additional components, are excluded from the scope of the claim. As the claim requires "sucralose and at least one or combination of" [sic] bulking agents, for purposes of examination, the claim will be interpreted as if written with the transitional phrase "comprising"

8. Regarding claim 3, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 3 recites the broad recitation of a bulk density ranging from 0.05 to 0.7 g/cc, and the claim

also recites ranges for bulk density ranging from 0.1 to 0.5 g/cc and 0.1 to 0.3 g/cc which are the narrower statements of the range/limitation.

9. Regarding claims 8 and 10, step II requires that the solution of sucralose be adsorbed to the bulking agent by "pouring it on the solution." It is unclear if the sucralose solution is to be poured onto the bulking agent, or if the bulking agent, presumably in a powdered form, is to be poured into the solution of sucralose. Clarification is required.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Barndt et al. (6,423,358).

12. Barndt et al. teach a sweetening composition comprising sucralose in combination with inulin and maltodextrin (low-density bulking agents). A specific example of the bulk density of the composition is 0.1 g/cc for a composition comprising sucralose:inulin/maltodextrin in a ratio of 1.2:98.8 (col. 3 lines 31-33). These teachings anticipate Applicant's claims 1-4.

13. Regarding claim 5, Barndt et al. are silent as to the bulk density of the bulking agent(s) when not combined with the sucralose. However, as the final bulk density of the composition is within Applicant's claimed range, it is considered inherent that the bulking agent(s) themselves have a bulk density within Applicant's claimed range.

14. Regarding claim 7, the inulin and maltodextrin may be present in the composition ranging from 20 to 100% inulin and 0 to 80% maltodextrin (col. 3 lines 12-15), encompassing Applicant's claimed range.

15. Claims 1, 4, and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Song et al. (5,227,182).

16. Song et al. teach a composition comprising sucralose and a low density bulking agent (cellulose) (Abstract). These teachings anticipate Applicant's claims 1 and 4.

17. Regarding claims 8-10, Song et al. teach a method for making their composition comprising dissolving sucralose in a solvent, including an aqueous solvent or methanol (col. 4 lines 14-24). The sucralose solution is then mixed with the agglomerating agent and then ground to a specific particle size (col. 5 lines 40-54).

18. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hough et al. (CA 1076110).

19. Example 6 teaches a bulk sweetener comprising sucralose and maltodextrin and having a bulk density of 0.2 g/cc. These teachings anticipate Applicant's claims 1-4.

20. Regarding claim 5, Barndt et al. are silent as to the bulk density of the bulking agent(s) when not combined with the sucralose. However, as the final bulk density of the composition is within Applicant's claimed range, it is considered inherent that the bulking agent(s) themselves have a bulk density within Applicant's claimed range.

21. Regarding claim 6, the composition may comprise bulking agents including sucrose and maltodextrin (p. 4 lines 17-28).

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

23. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barndt et al. (6,423,358).

24. Barndt et al. teach several methods for producing their granular composition including drying mixing, co-spray drying, co-freeze drying, and blending among others. They further state that table top products are produced having densities ranging from 0.1 g/cc to 0.8 g/cc (col. 2 lines 54-67).

25. While Barndt et al. do not specifically teach dissolving the sucralose in a solvent to be combined with the bulking agent, one of ordinary skill reading the teachings of Barndt et al. would have understood that the material to be spray-dried or freeze dried

started out as a wet solution. Further, one of ordinary skill wishing to provide a final bulk density to result in a sweetening product having the same sweetness as sucrose on a volume to volume basis would have been able to determine the appropriate granular size fraction in order to provide the desired volume of the sweetening composition. This would not have required undue experimentation, and there would have been a reasonable expectation that based on the variety of methods taught by Barndt et al., any of a number of methods of making the sweetening composition would have provided the desired composition without undue experimentation.

26. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hough et al. (CA 1076110).

27. Hough et al. teach a granular sucralose composition as detailed above. The sucralose may be present in combination with one or more low bulk density bulking agents in order to provide the composition with a sweetness and volume approximately equivalent to that of sucrose (p. 4 lines 17-28).

28. Hough et al. are silent as to the ratio when a combination of two bulking agents are present.

29. However, one of ordinary skill in the art at the time the invention was made would have been familiar with bulking agents commonly blended with sucralose in order to provide a sweetening composition having a sweetness and volume to approximate that of sucrose. One of ordinary skill would have been able to determine an acceptable ratio of the bulking agents in order to result in a final product having the desired bulk density

as well as acceptable organoleptic properties. This would not have required undue experimentation, and there would have be a reasonable expectation of success.

30. Regarding claims 8-10, Hough et al. teach sucralose in combination with a solution of maltodextrin. That solution is then dried to a bulk density of 0.2 g/cc and is stated to have the same sweetness as an equivalent volume of sucrose.

31. Hough et al. do not speak to the solvent system, however, as noted in the objection to claim 9, any solvent system is considered to meet the limitation of being either aqueous or non-aqueous. Hough et al. further do not speak to sizing the material through a sieve to achieve the appropriate particle size.

32. As Hough et al. teach that their composition consisting of sucralose and maltodextrin a bulk density of 0.2 g/cc in order to provide the composition with the same sweetness as the equivalent volume of sucrose, the sizing of the granules through a sieve in order to provide the composition with the desired granule size to provide a composition having the same sweetness as the equivalent volume of sweetness is considered to be obvious. One of ordinary skill would have been able to select the appropriate drying method in order to provide particles of the desired size, whether through sieving or spray-drying. Both methods would have provided the predictable result of particles having a desired size to result in a bulk density to provide a sweetening composition have the same sweetness as the equivalent volume of sucrose. Further, undue experimentation would not have been required for one of ordinary skill to select a suitable drying method.

Double Patenting

33. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

34. Claims 1-10 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-10 of copending Application No. 11/296580. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

35. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. All of EP0545890, JP 2000-37169, JP 2002-136270, WO 99/30577, and US 2004/0258822 teach combinations of sucralose and bulking agents that may be used as granular, free-flowing substitutes for sucrose have a sweetness equivalent to sucrose on a volume to volume basis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571) 270-

3435. The examiner can normally be reached on Monday-Friday 7:30-5:00 EST (second Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. H. D./

Nikki H. Dees
Examiner
Art Unit 1794

/KEITH D. HENDRICKS/
Supervisory Patent Examiner, Art Unit 1794